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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,380	04/01/2002	Fabrizio Samaritani	P/42-63	7114

7590 06/13/2003

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EXAMINER
DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,380	SAMARITANI ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/1/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Status of Application, Amendments and/or Claims

The information disclosure statement filed 03 December 2001 (Paper No. 3) was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

The amendment filed 01 April 2002 (Paper No. 7) has been entered in full. Claims 1-10 are under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fabbri *et al.*, US Patent No. 5,017,557 in view of Samaritani, WO 95/35116. Fabbri *et al.* teach that GRF can be administered by the intravenous route (column 2, lines 47-52). In the clinical trial reported, GRF-29 was used in the form of lyophilized ampoules containing 100 or 150 micrograms and 10 milligrams of mannitol as excipient (claims 1, 2). The lyophilized substance, dissolved in 2 ml of physiologic saline, was administered by the intravenous route (column 2, lines 53-59)(claims 6, 8, 9). Fabbri *et al.* do not teach the use of saccharose in pharmaceutical compositions.

Samaritani teaches pharmaceutical compositions comprising human growth hormone (HGH) and saccharose (page 1, lines 1-8). Samaritani teaches pharmaceutical compositions comprising HGH and saccharose, alone or in combination with other stabilizing agents (page 4, lines 17-21)(claim 3). Samaritani teaches a process for the preparation of the pharmaceutical composition comprising the step of lyophilizing an aqueous solution of the components in the containers (page 4, lines 22-31)(claim 7). Samaritani teaches a solid mixture of HGH and saccharose reconstituted in a solution that is buffered with NaOH so that the pH equals 7.5 (page 10, lines 15-29)(claim 10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Fabbri *et al.* and Samaritani to make the instant invention of a pharmaceutical composition comprising GRF and saccharose. The motivation and expected success is provided by Samaritani who teaches that highly purified proteins are stabilized with saccharose.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fabbri *et al.*, US Patent No. 5,017,557 in view of Samaritani, WO 95/35116 and further in view of Fujioka *et al.*, US Patent No. 4,963,529. The teachings of Fabbri *et al.* are described above. Fabbri *et al.* does not teach 10mg/vial of hGRF or 68.4 mg/vial of saccharose.

Samaritani teaches 68.4 mg/vial of saccharose (page 6, lines 5-14). Fujioka *et al.* teach the lyophilization of a composition comprising 10 mgs/vial of GRF (column 3, lines 25-55)(claims 4, 5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Fabbri *et al.*, Samaritani and Fujioka *et al.*, to make the instant invention of a pharmaceutical composition comprising 10mg/vial GRF and 68.4 mg/vial of saccharose. The motivation and expected success is provided by Samaritani who teaches that highly purified proteins are stabilized with saccharose and Fujioka *et al.*, who teach the different concentrations of GRF.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

RMD
June 11, 2003

ELIZABETH KEMMERER
PRIMARY EXAMINER